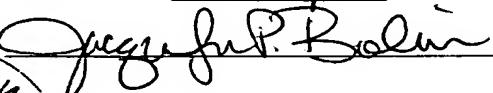


I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 14, 2006



Jacquelyn P. Bolin

Attorney Docket No. CHM-015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Prasad DEVARAJAN et al.

Serial No.: 10/811,130

Filed: March 26, 2004

A METHOD AND KIT FOR DETECTING THE EARLY  
ONSET OF RENAL TUBULAR CELL INJURY

Confirmation No: 2792

Group Art Unit: 1641

Examiner: FOSTER, Christine E

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 CFR 1.56, 1.97 and 1.98**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the above-identified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of the non-patent literature.

Applicants also respectfully request the Examiner to consider and make of record the co-pending application listed on the attached page.

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

This submission does not represent that a search has been made or that no closer art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully submitted,

For: Prasad DEVARAJAN et al.

By

  
\_\_\_\_\_  
Daniel F. Nesbitt  
Attorney for Applicant  
Registration No. 33,746  
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Customer Number 38155

November 14, 2006

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

NOV 16 2006

(use as many sheets as necessary)

Sheet

1

of

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<i>Complete if Known</i>	
Application Number	10/811,130
Filing Date	03/26/2004
First Named Inventor	DEVARAJAN et al.
Art Unit	1641
Examiner Name	FOSTER, CHRISTINE E
Attorney Docket Number	CHM-015

## U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 5,945,294	08-31-1999	Frank et al.	
		US- 6,221,625	04-24-2001	Ashihara et al.	
		US- 6,664,385	12-16-2003	Sanicola-Nadel et al.	

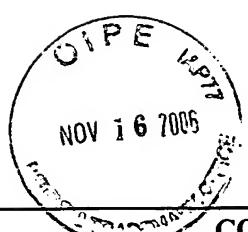
## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Biomarkers Definitions Working Group, Biomarkers and Surrogate Endpoints: Preferred Definitions and Conceptual Framework, <i>Clinical Pharm. &amp; Therapeutics</i> , vol. 69, No.3, March 2001, P. 89-95.	
		Definition for term “ELISA”, <a href="http://www.thefreedictionary.com">www.thefreedictionary.com</a> (1 page)	
		DEVARAJAN, P, Novel biomarkers for the early prediction of acute kidney injury; <i>Cancer Therapy</i> (2005); Vol. 3, pp. 477-488	
		ELNEIHOUM, A.M., et al., Leukocyte activation in atherosclerosis; correlation with risk factors, <i>Atherosclerosis</i> , 1997 May; 131(1): 79-84	Abstract
		HRUBEC et al, Plasma Versus Serum: Specific Differences in Biochemical Analyte Values” <i>Journal of Avian medicine and Surgery</i> 16(2):101-105,2002	
		KRAMER, A. A., et al.; Renal ischemia/reperfusion leads to macrophage-mediated increase in pulmonary vascular permeability; <i>Kidney International</i> (1999), Vol. 55; pp. 2362-2367	
		Medline Plus Medical Encyclopedia, “Serum Hemoglobin”, <a href="http://www.nlm.nih.gov/medlineplus/ency/article/003677.htm">www.nlm.nih.gov/medlineplus/ency/article/003677.htm</a> .	
		RABB, H., et al., Acute renal failure leads to dysregulation of lung salt and water channels; <i>Kidney International</i> (2003); Vol. 63; pp. 600-606	
		SCHMIDT-OTT, K. M., et al.; Neutrophil gelatinase-associated lipocalin-mediated iron traffic in kidney epithelia; <i>Current Opinion in Nephrology and Hypertension</i> (2006); Vol. 15:000-000 pp. 1-8	

Examiner Signature		Date Considered	
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## COPENDING U.S. PATENT APPLICATION

Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.
	BARASCH, et al.	11/374,285	10/13/2005	CHM-032

Examiner Signature		Date Considered	
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